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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,900	02/24/2004	Eugene R. Cooper	029318-1003	1015

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

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11/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/784,900	COOPER ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *26-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 50-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 26-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/29/09.

Applicant's election with traverse of Group I (claims 1-25 and 50-72) in the reply filed on 06/29/09 is acknowledged. The traversal is on the ground(s) that the search and examination of the two Groups of claims is not unduly burdensome to the Examiner, and that the restriction requirement is improper at this stage of prosecution. This is not found persuasive because:

1) restriction requirement is normally be made before any action upon the merits; however, it may be made at any time before final action. This means the examiner should make a proper requirement as early as possible in the prosecution, in the first action if possible, otherwise, as soon as the need for a proper requirement develops. See 37 CFR 1.142(a); and

2) requirement for restriction practice are set forth in MPEP§803.

There are two criteria for a proper requirement for restriction between patentable distinct inventions:

i) The inventions must be distinct as claimed (see MPEP§§806.05-806.05(i)); and

ii) There must be a serious burden on the examiner if restriction is not required (see MPEP§§803.02, 806.04(a)-(j), 808.01(a) and 808.02).

In response to applicant's arguments that *the search and examination of the two Groups of claims is not unduly burdensome to the Examiner*, it is noted that method and product are statutorily distinct categories of invention, and the particular method claimed is distinct from the particular product claimed because there is an alternative method for making the product. Therefore, there is no reason why a search for the method must include a search for the product as well. The existence of an alternative method of making the product, as well as the different classification of two inventions, provides evidence of a burden on the examiner in examining both inventions. Distinctness between a process of making and the product made is shown if "the product as claimed can be made by another materially different process." MPEP§806.05(f). Applicant has not alleged that either product or process claims were improperly classified. Nor has applicant alleged that the classifications set forth are not "separate classifications.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

Claims 1-17 and 50-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struengmann et al. WO 99/09988 A1, in view of Bosch et al. US 5,510,118.

Struengmann teaches a pharmaceutical composition comprising micronized meloxicam with suitable additive such as microcrystalline cellulose and/or surfactant and/or co-solvent (page 3; and examples). Surfactant is disclosed at page 4, last paragraph bridging page 5. Co-solvent includes propylene glycol, polyethylene glycol,

glycerol and ethanol (page 3, last paragraph). The obtained meloxicam is then incorporated into dosage forms include controlled release oral composition, tablet, sachet, ointment, suppositories, and hydrogel (page 5, paragraphs 35).

Struengmann does not expressly teach the particle diameter of the micronized meloxicam. However, absent of evidence to the contrary, the burden is shifted to applicant to show that the obtained meloxicam powder of Struengmann does not have the claimed average particle size. However, to be more specific, Bosch teaches a process of preparing nanoparticulate drug substances comprising the steps of dispersing a crystalline drug in a liquid dispersion medium containing a surface modifier, and subjecting the premix to mechanical means to reduce the particles size of the drug substance to less than 400 nm (abstract; column 4, lines 3-10; and column 7, lines 40 through column 8, lines 1-40). Drug includes water-insoluble drug substance such as an NSAID substance (column 5, lines 1-2; and table 1). Surface modifier includes nonionic, anionic, organic, inorganic excipients, and mixture of two or more (column 5, lines 45 through column 6, lines 1-29). Bosch further teaches the surface modifier is adsorbed on the surface of the drug substance, but the individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages (column 6, lines 29-35).

Thus, it would have been obvious to one of ordinary skill in the art to modify the meloxicam composition of Struengmann to obtain a nanoparticulate meloxicam composition in view of the teachings of Bosch. This is because Bosch teaches a nanoparticulate composition that exhibits remarkably high bioavailability (column, lines

12-13), because Bosch teaches a process suitable for a wide variety of active agents including NSAIDs, because Struengmann teaches the desirability for obtaining a composition with high bioavailability, and because Struengmann teaches reducing particle size of meloxicam by micronisation (page 3, last paragraph; page 10; and examples).

It is noted that Struengmann does not explicitly teach the claimed properties such as the T_{max} or C_{max} values of the NSAID. However, the burden is shifted to applicant to show that the meloxicam composition of Struengmann does not necessarily produce the T_{max} or C_{max} value being claimed. This is because Struengmann teaches a meloxicam composition having an improved bioavailability and solubility of meloxicam (abstract; page 1, first paragraph; and examples).

Claims 18-25 and 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struengmann et al., in view of Desai et al. WO 01/45706 A1 or Courteille et al. US 5,384,124.

Struengmann is relied upon for the reasons stated above. Struengmann does not teach the second particle population.

Desai teaches a dual-release composition of low water soluble drug (COX-2 inhibitor) comprising first fraction of the drug in nano-particulate form having average diameter of about 200 to about 400 nm and a D90 particle size less then about 5 μm (page 18); and a second fraction of the drug in micro-particulate form having D_{10} particle size of between 25 to about 100 μm (page 20, 1st paragraph). The first fraction nano-

particle drug can be present alone or in combination with one or more excipient, such as nano-particles of the drug have a surface modifying agent (PEG-400) adsorbed on the surface thereof (page 18, 3rd through page 19). The weight ratio of the first to the second fraction of the drug in the composition is about 1:10 to about 10:1 (page 22, 3rd paragraph). The composition can be in an oral dosage form including tablet, pills, hard or soft capsule, lozenges, cachets, dispensable powder, granule, suspension or elixir (pages 37-38).

Courteille teaches a solid unitary composition comprising combination of nano-particle having diameter of less than 1 μm and micro-particle having diameter of between 1 μm to 2 mm (see abstract, column 2, lines 32-46). The mixture of nano/micro-particle contains one or more active agents of the same or different type (column 1, lines 66-68, and column 2, lines 23-31). The active agent can be selected from antibiotic, analgesic, tranquilizer, vitamins, and therapeutic agents for diseases of allergies, hormones, or gastrointestinal tract (column 5, lines 46-66). The mixture of nano/micro-particle is prepared by any known method (air-fluidized bed coating, turbine coating, simple extrusion, or micro-encapsulation) employing the use of a polymer or a macromolecular substance (surface stabilizer) selected from the group of cellulose derivatives, starch, polyamide, collagen, dextrin, gelatin, polyvinyl chloride or the like (column 2, lines 46-55, and column 3, lines 18-40). The mixture further comprises stabilizing agent, surfactant, and biding agent (column 4, lines 20 through column 5, lines 1-28). Courteille further teaches the solid dosage form comprises immediate release with a secondary controlled release of mixture of nano/micro-particle (column 6,

lines 16-50). The solid dosage form is to be incorporated into pharmaceutical oral dosage form (column 6, lines 51-56).

Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Struengmann to include the second particle population in view of the teachings of Desai or Courteille, because Desai and Courteille teach compositions suitable for analgesic substance, because Desai and Courteille teach that combination of one or more population of active substance with different particle size is well known in the art, and because Struengmann teaches the desirability for formulating a controlled release composition comprising different layer having different release profiles (page 5, 3-4 paragraphs).

Response to Arguments

Applicant's arguments filed 06/29/09 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that Bosch describes a genus of drug substances encompassing over 40 categories of drugs and each drug category comprises an enormous number of members. First, Bosch lacks any suggestion to preferentially select analgesics or anti-inflammatory agents out of over 40 categories of the drugs. Second, anti-inflammatory agents encompass a large family of drugs, including steroidal anti-inflammatory drugs and non-steroidal anti-inflammatory drugs. A quick search of the drug bank using the keyword "anti-inflammatory drugs" returned 767 entries.

However, it is of note that Bosch specifically preferred the use of analgesics and/or anti-inflammatory agent including naproxen. Bosch further discloses specific example using naproxen. See Table 1. Accordingly, one of ordinary kill in the art would have been motivated to, by routine experimentation select an analgesic and/or anti-inflammatory agents.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615